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Developing Quality Assurance Programs That Satisfy 10 CFR 71, Subpart H and Department of Energy Requirements For Packaging Organizations at Department of Energy Sites

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DEVELOPING QUALITY ASSURANCE PROGRAMS THAT SATISFY 10 CFR 71, SUBPART H AND DEPARTMENT OF ENERGY REQUIREMENTS FOR PACKAGING ORGANIZATIONS AT DEPARTMENT OF ENERGY SITES

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ABSTRACT

Many differences exist in Department of Energy (DOE) and Nuclear Regulatory Commission (NRC) Quality Assurance (QA) requirements documents, work scope, organizational structures, and graded application and assessment approaches. These differences must be understood and reconciled to ensure consistent and effective implementation and cost effective assessments of QA Programs for DOE organizations participating in the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, use and/or modification of the radioactive material packaging.

This paper discusses those differences and provides practical recommendations that can serve as stepping stones to more effective and efficient QA programs and value added assessments at DOE sites participating in radioactive material packaging activities.

INTRODUCTION

The January 2004 revision of 10 CFR 71 (Ref. 1) effective October 1, 2004 adds a new requirement for the NRC to perform independent oversight of DOE organizations participating in the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, use and/or modification of the radioactive material packaging.

Disparities exist between DOE 10 QA criteria and NRC 18 QA criteria requirements documents at DOE sites and the DOE and NRC approaches for graded application of these requirements. These differences cause difficulties in interpretation and implementation of the 10 CFR 71, Subpart H requirements at DOE sites and can result in serious impacts on overall compliance of a DOE applicant's QA Program with 10 CFR 71, Subpart H and costs of QA program implementation and oversight. In addition, the scope of package-related activities at DOE sites extends beyond those of the "user" as is typically the case in NRC regulated nuclear facilities. Organizational reporting lines for packaging organizations at DOE sites can also be extremely complex.

Packaging activities at DOE sites are assessed under the DOE nuclear safety enforcement program which requires DOE sites to voluntarily identify and report noncompliances with DOE nuclear safety requirements, thereby allowing DOE to effectively regulate its nuclear operations without the undue expense and resources required for inspections by outside regulatory agencies.

The differences in DOE and NRC QA requirements, work scope, organizational structures, and graded approach and assessment applications hinder effective implementation and assessment of 10 CFR 71, Subpart H requirements at DOE sites. Understanding and reconciling these difference will result in improved implementation of 10 CFR 71 by DOE organizations and increased value of assessments of packaging related activities at DOE sites.

DIFFERENCES IN NRC AND DOE QA REQUIREMENTS FOR RADIOACTIVE MATERAL PACKAGING ACTIVITIES

At the highest level, QA Programs at DOE sites implement the 10 criteria of DOE 5700.6C (Ref. 2), DOE Order 414.1A (Ref. 3), or DOE Order 414.1B (Ref. 4) based on contractual requirements in effect. However, organizations and facilities at these sites that participate in packaging and transportation activities are required to develop supplemental QA programs that meet the 18 QA elements of 10 CFR 71, Subpart H and frequently the 10 QA criteria of 10 CFR 830.122 (Ref. 5), the "QA Rule." These requirements documents specify what QA requirements the applicant must meet but do not specify how to implement the requirements. The only available standards and guidance documents that provide methods for meeting the QA requirements are developed by the NRC and are tailored to NRC nuclear facilities operating under 10 CFR 50, Appendix B (Ref. 6) 18 criteria, NRC approved QA Programs. DOE orders, on the other hand, are in general more performance-based with less emphasis on independent assessment and more on self-assessment. Reconciliation of these differences can be labor intensive and interpretation can be inconsistent across the DOE complex.

Tailoring packaging QA standards to DOE sites is especially important since the difficulties in interpreting 10 and 18 QA criteria requirements documents are compounded by the uniqueness in the packaging activities and complexities in reporting lines and structures of packaging organizations at DOE sites. Several layers of complexity are added, for example, if the QA program for packaging is invoked and managed at an institutional level at a DOE site, but the packaging-related activities are performed by one or more organizations in one or more facilities managed by one or more organizations across a site or sites.

NRC guidelines are tailored to NRC regulated nuclear facilities that are the traditionally the "user" of the package. The NRC also audits companies that fabricate and supply packages to NRC regulated facilities. A DOE package user, on the other hand, is also frequently the package designer, purchasing agent, and sometimes the package fabricator. At DOE sites, several organizations and facilities may be involved in one or more activities related to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, use and/or modification of the radioactive material packaging. DOE sites also are responsible for assessing performance of their package suppliers.

If packaging and transportation activities are performed in nuclear facilities at DOE sites, another layer of complexity is added since the QA Rule now takes precedence. The QA Rule specifically excludes packaging and transportation activities regulated by the NRC and Department of Transportation (DOT) and, at first glance, gives the appearance that the QA Rule does not affect these activities. However, this is not accurate. Since activities related to the packaging and transportation of radioactive material are performed in nuclear facilities and can impact facility nuclear safety, they, too, are included in the scope of the QA Rule and are subject to Price-Anderson Amendments Act (PAAA) penalties.

The disparities in QA criteria and their application and scope in 10 CFR 71, Subpart H, the QA Rule and DOE QA Orders pose serious challenges to DOE packaging organizations when more than one of these documents apply. DOE QA orders endorse the development of one integrated QA program when multiple QA requirements apply but no formal guidance exists for accomplishing this effectively and efficiently.

Those who choose to develop two QA programs are at risk of developing redundant QA systems. They, on the other hand, may choose to develop 10 criteria QA programs that are not standards-based and do not necessarily comply with the 18 criteria of 10 CFR 71, Subpart H. In addition, the facility must establish methods for assuring tenants participating in packaging and transportation activities, their vendors, and associated procurements comply with the facility QA program.

Because QA standards tailored to DOE packaging and transportation activities do not exist, DOE organizations that engage in these activities frequently develop NQA-1 (Ref. 7) 18 QA criteria based QA programs or 10 QA criteria based QA programs that are "forced to fit" into but do not necessarily meet the 18 QA criteria of 10 CFR 71, Subpart H and that may not be suited to the risk level, complexity, or scope of the work activities.

DIFFERENCES IN NRC AND DOE GRADED APPROACHES FOR APPLYING QA PROGRAMS

Major differences exist between the NRC and DOE graded approaches for classifying structures, systems, and components (SSCs) for radioactive material packaging and selectively applying QA programs to packaging activities and SSCs.

The requirements in 10 CFR 71, Subpart H and the NRC guidance in Regulatory Guide 7.10 (Ref. 8), and NUREG/CR-6407 (Ref. 9) for classifying package SSCs do not align with the safety analysis criteria and definitions for safety significant, safety related, important to safety, and defense in depth in DOE-STD-3009-94 (Ref. 10) and 10 CFR 830.122. While the NRC criteria for classifying SSCs focus primarily on evaluating impacts of hazards to the public, the DOE criteria include impacts to the worker, co-located worker, and environment.

The DOE graded approach criteria for applying QA program controls include evaluation of impacts to other risk-related areas such as cost and schedule, safeguards and security, public opinion, mission criticality, and work complexity. Terminology and definitions related to risks and graded approach applications also vary in the NRC and DOE.

DOE packaging organizations are left unguided to resolve these differences and to fit their risk criteria into ones suited to different work risks, scope, and applications in NRC regulated nuclear facilities.

OVERSIGHT OF DOE PACKAGING ACTIVITIES

Packaging activities at DOE sites must meet the requirements of the DOE Nuclear Safety Rules, established in accordance with PAAA and are subject to enforcement by the DOE Office of Enforcement and Investigation (EH-Enforcement). The term "DOE Nuclear Safety Rules" refers to four parts of the U.S. Code of Federal Regulations:

1. 10 CFR 820, "Procedural Rules for DOE Nuclear Activities," particularly Section 820.11, "Information Requirements." (Ref. 11)

2. 10 CFR 830, "Nuclear Safety Management." (Ref. 12)

3. 10 CFR 835, "Occupational Radiation Protection." (Ref. 13)

4. 10 CFR 708, "DOE Contractor Employee Protection Program." (Ref. 14)

EH-Enforcement serves as the regulatory authority for all contractor facilities and activities subject to DOE nuclear safety requirements. All DOE sites must implement the PAAA requirements for identifying, reporting, and tracking noncompliances with these DOE nuclear safety requirements. The DOE nuclear safety enforcement program relies on contractors to voluntarily identify and report noncompliances with DOE nuclear safety requirements, thereby allowing DOE to regulate its nuclear operations without the expense and intrusiveness of a regulatory inspection-based system. Implementation of the PAAA also includes a system of routine checks and balances that includes self-reporting of PAAA violations, independent and self-assessments, and reviews of other problem reports for identification of potential PAAA violations.

Since oversight of DOE packaging activities is already being performed as required by the DOE nuclear safety requirements, the value of NRC independent oversight inspections of packaging-related activities across the DOE complex as required by the new revision of 10 CFR 71, Subpart H is not readily apparent. It may be more cost efficient and effective for DOE and/or the NRC to "bless" or endorse the PAAA system for identifying, reporting, and tracking noncompliances with DOE nuclear safety requirements and for DOE to supplement the monitoring of packaging under PAAA with value added assessments.

The DOE could, for example, require DOE site self-assessments of their organizations working to 10 CFR 71, Subpart H QA Programs with results reported into a nationwide database that is evaluated for trends. DOE, based on trend analysis results, can then selectively perform independent assessments or request further actions from affected DOE sites.

The DOE could also require DOE applicants to submit their Subpart H QA Plans with the Safety Analysis Report for Packaging (SARP) when a SARP is generated or when the Certificate of Compliance for packaging is up for renewal. The QA Plan and SARP could then be reviewed by the SARP review group and comments on the QA Plan and SARP could be resolved concurrently by the applicant. This would also make the QA Plan available to SARP reviewers and would streamline and enhance the SARP Review Process.

CONCLUSIONS

The DOE and NRC can collaboratively develop several practical solutions to reconcile differences in DOE site-specific (10 QA elements) and package-specific (18 QA elements) requirements documents and graded application and assessment approaches. These solutions will help to ensure value added assessments of DOE organizations implementing 10 CFR 71, Subpart H QA programs.

First, the DOE should develop a risk-based DOE implementation guide (similar to Regulatory Guide 7.10) to serve as a QA standard that is tailored to the DOE graded approach for design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, use and/or modification of packaging. Include practical solutions for reconciling the disparities between 10 QA criteria and 18 QA criteria based regulations when both apply. The standard could also include matrices that diagram how its QA elements align with 10 CFR 71, Subpart H, 10 CFR 830.122, DOE 5700.6C, DOE Order 414.1A, DOE Order 414.1B and any other applicable DOE requirements documents.

DOE should also develop a training course that address the disparities in DOE and NRC requirements and provides guidance on developing QA programs that effectively and efficiently address the 18 QA requirements in 10 CFR 71, Subpart H and the 10 QA requirements in prevailing DOE documents.

Since oversight of packaging activities is currently being performed as required by the DOE nuclear safety requirements, it may be more cost efficient and effective for DOE and/or the NRC to endorse the PAAA system for identifying, reporting, and tracking noncompliances with DOE nuclear safety requirements.

DOE sites should supplement the PAAA self-reporting system with assessments of packaging organizations implementing Subpart H QA Programs.

In addition, DOE applicants should be required to submit their Subpart H QA Plans with the SARP to facilitate improvements to the QA Plans and the SARP and to enhance the SARP review process.

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